

Richard Thwaites, University of North Texas Health Science Center at Fort Worth: Based on an investigation conducted by the institution, ORI found that Richard Thwaites, former medical student, engaged in scientific misconduct by fabricating data in a clinical trial study supported by a Public Health Service (PHS) grant.

Mr. Thwaites has entered into a Voluntary Exclusion Agreement with ORI in which he has accepted ORI's finding and, for the three (3) year period beginning October 3, 1995, has voluntarily agreed to:

- (1) exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government, as defined in 45 C.F.R. Part 76 and 48 C.F.R. Subparts 9.4 and 309.4 (Debarment Regulations); and
- (2) exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

No scientific articles were published that relied on the fabricated data.

FOR FURTHER INFORMATION CONTACT:
Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852.
Chris B. Pascal,
Acting Director Office of Research Integrity.
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Centers for Disease Control and Prevention

[INFO-95-04]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-3453.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Wilma Johnson, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Projects

1. Phase 2, 1996 National Health Interview Survey, Basic Module (0920-0214)—The annual National Health Interview Survey (NHIS) is a basic source of general statistics on the health

of the U.S. population. Due to the integration of health surveys in the Department of Health and Human Services, the NHIS also has become the sampling frame and first stage of data collection for other major surveys, including the Medical Expenditure Panel Survey, the National Survey of Family Growth, and the National Health and Nutrition Examination Survey. By linking to the NHIS, the analysis potential of these surveys increases. The NHIS has long been used by government, university, and private researchers to evaluate both general health and specific issues, such as cancer, AIDS, and childhood immunizations. Journalists use its data to inform the general public. It will continue to be a leading source of data for the Congressionally-mandated "Health US" and related publications, as well as the single most important source of statistics to track progress toward the National Health Promotion and Disease Prevention Objectives, "Healthy People 2,000."

Because of survey integration and changes in the health and health care of the U.S. population, demands on the NHIS have changed and increased, leading to a major redesign. Improved information technology is planned, especially computer assisted personal interviewing (CAPI.) This clearance is for a one-time data collection, to introduce, test, and evaluate the redesigned NHIS data system. This data collection, planned for July-December 1996, is also expected to produce data of sufficient quality to allow publication of national estimates and release of public use micro data files. The resulting new NHIS data system is expected to be in the field for at least 10 years, beginning in January, 1997. Separate clearance will be requested for the post-1996 period.

| Respondents | No. of respondents | No. of respondents/respondents | Avg. burden/responses (in hours) | Total burden |
|--------------------|--------------------|--------------------------------|----------------------------------|--------------|
| Family | 10,500 | 1 | 0.5 | 5,250 |
| Sample adult | 10,500 | 1 | 0.5 | 5,250 |
| Sample child | 4,500 | 1 | 0.25 | 1,125 |
| | | | | 11,625 |

2. Evaluation of The National Laboratory Training Network (NLTN)—(New)—The National Laboratory Training Network (NLTN) was established in 1989 to provide education and training to different levels of laboratory personnel in public

health, private, independent laboratories and blood banks. Training in testing skills required to diagnose and monitor HIV infected individuals and AIDS-related diseases was the driving force behind its development. However, NLTN staff has responded to other

emerging training needs such as those required to test for *Mycobacterium tuberculosis*, Hantaviruses, and other diseases.
The NLTN works primarily with the State Public Health Laboratories forming partnerships that facilitate laboratory

training in most laboratory settings. This project is an evaluation of the effectiveness of the NLTN in meeting its goals and in satisfying the needs of its customers. Recipients of training and their supervisors will be the major sources of information. Some

assessment of participants that have not attended NLTN courses will be necessary to use as a control group.

Surveys will be directed to all types of laboratories that perform diagnostic testing. Samples will be selected from local health department laboratories,

state health department laboratories, microbiology course participants and physician office laboratories. The study was designed in FY 1994 and FY 1995. Data collection should begin late in FY 1995 and be completed in FY 1996.

| Respondents | No. of respondents | No. of responses/ respondents | Avg. burden/response | Total burden |
|--------------------|--------------------|-------------------------------|----------------------|--------------|
| Laboratories | 10,000 | 1 | .5 | 5,000 |

Dated: October 6, 1995.

Joseph R. Carter,

Acting Associate Director for Management And Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95-25443 Filed 10-12-95; 8:45 am]

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National Committee on Vital and Health Statistics (NCVHS) Executive Subcommittee; Meetings

Pursuant to Pub. L. 92-463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following subcommittee meetings.

Name: NCVHS Executive Subcommittee.

Time and Date: 9 a.m.-5 p.m., November 8-9, 1995.

Place: Auditorium, Oakland Federal Building, 1301 Clay Street, Oakland, CA 94612-5217.

Name: NCVHS Executive Subcommittee.

Time and Date: 9 a.m.-5 p.m., December 5-6, 1995.

Place: Room 703A, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open.

Purpose: The purpose of this meeting is to obtain public comments and views toward identifying a set of core health data elements on persons and encounters or events that can serve multiple purposes and would benefit from standardization. This is a public-private collaborative effort by NCVHS to provide information and advice to the Department of Health and Human Services that would help maximize the utility of core person and encounter data and foster evolution of public and private health information systems toward more uniform, shared data standards. The Committee seeks through this effort to facilitate consensus development and build the concepts of multiple use, continued change, and long-term evolution of core data elements into general thinking and practice. The goal is to see what commonalities already exist and to what extent there can be further movement toward greater commonality of terms and consistency of definition. The Committee hopes to provide tentative recommendations to the Department's recently established Data Council by early 1996.

Matters to be Discussed: Comments and views of health data collectors and users will be sought on a list of potential core data elements, which includes those that have been recommended or considered by NCVHS for inclusion in the Uniform Hospital Discharge Data Set and Uniform Ambulatory Care Data Set. The list also includes additional elements frequently collected by selected public and private payers and health care plans, as identified through development of a working compendium of core data elements collected or proposed for collection regarding eligibility, enrollment, encounters, and claims in the United States. Agenda items are subject to change as priorities dictate.

Persons wishing to make oral comments at the meeting should notify the contact persons in writing or by telephone no later than the close of business on October 20, 1995. Written comments are welcome and should be reviewed by October 27, 1995. All request to make oral comments should contain the name, address, telephone number, and organizational affiliation of the presenter. Depending on the time available and the number of requests to make oral comments, it may be necessary to limit each presenter.

Comments received after October 27 but by November 17 will be considered at the December 5-6 meeting. Other oral comments and germane discussion will be accepted at the discretion of the chair and as time permits. Written comments from persons who do not expect to attend either the November 8-9 or December 5-6 meeting should be submitted to the general information contacts listed below. These comments will become a part of the official record of the meeting. Persons with disabilities who require special accommodations are requested to specify their needs in writing to the general information contact persons listed below by October 20, 1995.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, persons without a government identification card should plan to arrive at the building each meeting day either between 8:30 and 9:00 a.m. or 12:30 and 1:00 p.m. so they can be escorted to the meeting. Entrance to the meeting at other times during the day cannot be assured. In the interest of security at the Oakland Building, persons must present a picture

identification or sign in with the security guard.

Contact Persons for More Information.

Substantive program and technical information may be obtained from Lynnette Araki or Marjorie S. Greenberg, Office of Planning and Extramural Programs, (OPEP), NCHS, CDC, telephone number 301/436-7142, fax 301/436-4233. For general information on logistics and special needs as well as summaries of the meetings and a roster of committee members please contact Bette Darling, Program Development Staff, OPEP, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436-7122, fax 301/436-4233.

Dated: October 6, 1995.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95-25442 Filed 10-12-95; 8:45 am]

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Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part 56 FR 58250, on November 18, 1991) is amended to reflect an organizational change in the Center for Drug Evaluation and Research (CDER) in the Food and Drug Administration (FDA).

The Food and Drug Administration plans to realign its major human drug program functions into two primary lead areas: drug review management and pharmaceutical science. The Office of Review Management (ORM) and the Office of Pharmaceutical Science (OPS), each to be headed by a Deputy Center Director, will report directly to the Director of CDER. FDA believes this